



**ATO-P R&D**

**Human Factors Research and Engineering Division**

**Human Factors Newsletter**

**Special Edition**

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Researchers from the CAMI Aerospace Medical Research Division will be attending the Aerospace Medical Association Annual Conference, May 14-18, 2006. A list of their presentations is provided, followed by abstracts/summaries.

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*Topic: Aviation Medicine*

*Russell Lewis, Robert D. Johnson, Sabra Ruvera Botch, Dennis Vincent Canfield*

**THE PREVALENCE OF ILLICIT DRUGS IN US AVIATION ACCIDENT PILOT FATALITIES BETWEEN 1995 AND 2004: PART II, COCAINE**

INTRODUCTION: Cocaine is a widely abused illicit drug in America. Cocaine abuse transcends all social, racial, and economic boundaries. Demonstrating the presence or absence of cocaine and cocaine-related molecules in postmortem fluids and/or tissues of aviation accident victims can have serious legal consequences and may help determine the cause of impairment and/or death. METHOD: The Federal Aviation Administration's Forensic Toxicology Research Laboratory analyzes specimens collected from pilots involved in civil aviation accidents. Toxicological information on aviation fatalities was obtained from the toxicology database. Accident information, probable cause(s), and associated factors of an aviation accident were obtained from the National Transportation Safety Board (NTSB). RESULTS and DISCUSSION: Over the ten-year period, 1995-2004, there were 3,235 fatal aviation accidents, 24 of which tested positive for cocaine. Of these 24 cocaine-positive fatalities, the NTSB determined cocaine or a combination of cocaine and other drugs as being the probable cause in five accidents, and a factor in an additional four accidents. Twenty-two of the 24 fatal accidents were operated as general aviation (14 CFR Part 91) and two as agriculture (Part 137). Twenty-three of the 24 fatal pilots were male. The mean age of the cocaine-positive pilots was 39 years. In addition to being positive for cocaine, 14 of the 24 tested positive for other disqualifying substances. Of these 14 victims, six contained ethanol at levels above the FAA ethanol cutoff, five were found positive for methamphetamine, three for marijuana, two for benzodiazepines, one for methylenedioxymethamphetamine (ecstasy, MDMA), one for propoxyphene, two for fluoxetine, and one for paroxetine. CONCLUSION: In cocaine-positive pilot fatalities, the use of cocaine was determined to be a cause or factor in nearly 38% of the accidents. However, based on the data presented here, cocaine use within the pilot population appears to be an infrequent and uncommon event.

*Summary: 1) the prevalence of cocaine use in general aviation accidents, 2) the role of toxicology in aviation accident investigation, and 3) Investigate the epidemiological aspects of cocaine-positive pilot fatalities.*

*Topic: Aviation Medicine*

*Dennis Vincent Canfield, Guillermo J. Salazar, Russell Lewis, James Elliott Whinnery*

### **COMPARISON OF PILOT MEDICAL HISTORY AND MEDICATION FOUND IN POSTMORTEM SPECIMENS**

Pilots are required by the Federal Aviation Administration (FAA) regulations to report all medications and medical conditions to the FAA Office of Aerospace Medicine for review and consideration as to the overall suitability of the pilot for flight activities. Specimens from deceased pilots are collected by local pathologists and sent to the Civil Aerospace Medical Institute for toxicological analysis. The results of such tests are entered into the Forensic Case Management System. This database was searched to identify all pilots found positive for medications used to treat cardiovascular, psychological or neurological conditions over the period January 1, 1993, through December 31, 2003. Our laboratory conducted toxicological evaluations on 4,143 pilots during the study period. Psychotropic drugs were found in 223 pilots (5%). Cardiovascular medications were found in 149 pilots (4%). Neurological medications were found in 15 cases (0.4%). Pilots reported psychological conditions in 14 of the 223 pilots found positive for psychotropic drugs. Only 1 of the 14 pilots reporting a psychological condition reported the psychotropic medication found after the accident on their medical application. Cardiovascular disease was reported by 69 of the pilots found to have cardiovascular drugs in their system. The cardiovascular medications found in the pilots were reported by 29 of the 69 pilots reporting a cardiovascular condition. Additionally, two pilots reported taking cardiovascular medications, but no cardiovascular medications were found in the postmortem specimens tested. Only one of the 15 pilots reported having a neurological condition on their medical application. Based on the drugs screened for by the laboratory, we successfully identified 93% of the medications reported by the pilots. Pilots involved in fatal accidents taking psychotropic or neurological medications rarely reported the medication or their underlying medical condition with the FAA Aerospace Medical Certification program, as required.

*Topic Summary: Medications found in pilots and the relationship between reported medical history and drugs found post accident.*

*Topic: Aviation Medicine*

*Robert D. Johnson Ph.D., Russell J. Lewis Ph.D, Sabra R. Botch, Dennis V. Canfield Ph.D.*

### **THE PREVALENCE OF ILLICIT DRUGS IN US AVIATION ACCIDENT PILOT FATALITIES BETWEEN 1995 AND 2004: PART I, MARIJUANA**

**INTRODUCTION:** Marijuana (tetrahydrocannabinol, THC) is possibly the most widely abused illicit drug in America. The side effects of marijuana use include difficulty thinking and loss of coordination. Demonstrating the presence of THC in postmortem specimens of aviation accident victims can have serious legal consequences and can help determine the cause of the aviation accident. **METHOD:** In fatal aviation accidents, specimens from accident victims are routinely sent to the Federal Aviation Administration's Forensic Toxicology Research Laboratory for toxicological analysis. Toxicological information from these analyses are stored in a database at the Civil Aerospace Medical Institute's (CAMI's) Forensic Toxicology Research Laboratory.

Case histories and accident information were obtained from the National Transportation Safety Board (NTSB). Results and Discussion: Over this 10-year period, there were 3235 fatal aviation accidents, 74 of which were found positive for THC. Of these cases, the NTSB reported THC as either the probable cause or a factor in 24 of the accidents (~32%). Of the 74 THC-positive pilot fatalities, 64 were operated as general aviation (14 CFR Part 91), four were operated as air taxi and commercial (Part 135), three were operated as agricultural (Part 137), and three were operated as ultra-lights (Part 103). Seventy-three of the pilots were male and one was female with a mean age of 36 years. In addition to a positive finding for THC, 24 of the 74 pilots tested positive for other disqualifying substances. Of these 24 victims, seven were positive for methamphetamine, six contained selective serotonin reuptake inhibitors (SSRIs), five contained ethanol, five positive for benzodiazepines, three for cocaine, and there was one positive each for opiates, tramadol, meperidine, and olanzapine. CONCLUSION: Fatal aviation accidents attributed to THC are an infrequent event, as THC use was found to contribute to only 0.74% of all fatal aviation accidents between 1995 and 2004.

*Topic Summary: 1) the prevalence of marijuana in general aviation accidents, 2) the role of toxicology in aviation accident investigation, and 3) epidemiological aspects of marijuana-positive pilot fatalities.*

*Topic: Aviation Medicine*

*Russell Lewis, Robert D. Johnson, Sabra Ruvera Botch, Dennis Vincent Canfield*

### **THE PREVALENCE OF ILLICIT DRUGS IN US AVIATION ACCIDENT PILOT FATALITIES BETWEEN 1995 AND 2004: PART II, COCAINE**

INTRODUCTION: Cocaine is a widely abused illicit drug in America. Cocaine abuse transcends all social, racial, and economic boundaries. Demonstrating the presence or absence of cocaine and cocaine-related molecules in postmortem fluids and/or tissues of aviation accident victims can have serious legal consequences and may help determine the cause of impairment and/or death. METHOD: The Federal Aviation Administration's Forensic Toxicology Research Laboratory analyzes specimens collected from pilots involved in civil aviation accidents. Toxicological information on aviation fatalities was obtained from the toxicology database. Accident information, probable cause(s), and associated factors of an aviation accident were obtained from the National Transportation Safety Board (NTSB). RESULTS and DISCUSSION: Over the ten-year period, 1995-2004, there were 3,235 fatal aviation accidents, 24 of which tested positive for cocaine. Of these 24 cocaine-positive fatalities, the NTSB determined cocaine or a combination of cocaine and other drugs as being the probable cause in five accidents, and a factor in an additional four accidents. Twenty-two of the 24 fatal accidents were operated as general aviation (14 CFR Part 91) and two as agriculture (Part 137). Twenty-three of the 24 fatal pilots were male. The mean age of the cocaine-positive pilots was 39 years. In addition to being positive for cocaine, 14 of the 24 tested positive for other disqualifying substances. Of these 14 victims, six contained ethanol at levels above the FAA ethanol cutoff, five were found positive for methamphetamine, three for marijuana, two for benzodiazepines, one for methylenedioxymethamphetamine (ecstasy, MDMA), one for propoxyphene, two for fluoxetine, and one for paroxetine. CONCLUSION: In cocaine-positive pilot fatalities, the use of cocaine

was determined to be a cause or factor in nearly 38% of the accidents. However, based on the data presented here, cocaine use within the pilot population appears to be an infrequent and uncommon event.

*Summary: Understand 1) the prevalence of cocaine use in general aviation accidents, 2) the role of toxicology in aviation accident investigation, and 3) Investigate the epidemiological aspects of cocaine-positive pilot fatalities.*

Topic: Aviation Medicine

Sabra Ruvera Botch, Russell Lewis, Robert D. Johnson, Dennis Vincent Canfield

**THE PREVALENCE OF ILLICIT DRUGS IN US AVIATION ACCIDENT PILOT FATALITIES BETWEEN 1995 AND 2004: PART III, METHAMPHETAMINE**

INTRODUCTION: Methamphetamine is an addictive stimulant drug that strongly activates certain systems in the brain. Methamphetamine abuse is one of the fastest growing epidemics in America. Upon toxicological analysis, a methamphetamine positive in postmortem fluids and/or tissues of aviation accident victims has serious legal consequences and may help determine the cause of an aviation accident. METHOD: In fatal aviation accidents, specimens from accident victims are routinely sent to the Federal Aviation Administration's (FAA's) Forensic Toxicology Research Laboratory for toxicological analysis. Toxicological information for the accidents in question was obtained from the Civil Aerospace Medical Institute's (CAMI's) Forensic Toxicology Research Laboratory database. Case histories and additional accident information were obtained from the National Transportation Safety Board (NTSB). RESULTS and DISCUSSION: Over the ten-year period, 1995-2004, there were 3235 fatal aviation accidents, 17 of which were positive for methamphetamine. Of these 17 methamphetamine-positive fatalities, the NTSB reported methamphetamine or a combination of methamphetamine and other drugs as being the probable cause in 12 of the accidents. Sixteen of the 17 fatal accidents were operated as general aviation (14 CFR Part 91) and one as agricultural aviation (Part 137). All 17 pilots were male with a mean age of 43 years. In addition to being positive for methamphetamine, 10 of the 17 tested positive for other disqualifying substances. Of these 10 victims, seven were found positive for marijuana, five positive for cocaine, one had consumed ethanol, one was positive for benzodiazepines, one for methylenedioxymethamphetamine (ecstasy, MDMA), one for fluoxetine, and one for tramadol. CONCLUSION: Fatal aviation accidents associated with methamphetamine use are an infrequent event, as methamphetamine use contributed to only 0.37% of all fatal aviation accidents between 1995 and 2004.

*Topic Summary: 1) the prevalence of methamphetamine use in general aviation accidents, 2) the role of toxicology in aviation accident investigation, and 3) Investigate the epidemiological aspects of methamphetamine-positive pilot fatalities.*

Topic: Neurophysiology / Vision

Kathryn J. Wood CPOT, Van Nakagawara O.D., Ron W. Montgomery B.S.

**LASER ILLUMINATIONS IN THE CIVIL AVIATION ENVIRONMENT.**

INTRODUCTION: Flight crewmember exposure to laser light, while operating an aircraft at night, has resulted in glare, flash-blindness, and after-image. Due to the distraction, disorientation, and discomfort that accompany temporary visual impairment, these events may create a hazardous situation. A database of aviation reports involving laser illumination of flight crewmembers has been established and maintained at the Civil Aerospace Medical Institute. A review of recent laser illumination reports was initiated to investigate the significance of these events. METHODS: Reports of high-intensity light illumination of aircraft were collected from Federal Aviation Administration (FAA) regional offices, Transportation Security Administration, Department of Homeland Security/Federal Bureau of Investigation Information Bulletins, Office of Accident Investigation reports, newspaper articles, and personal interviews with reporting and investigating personnel. Those reports that involved laser exposures of civilian aircraft in the United States were collated and analyzed for the 13-month period (January 1, 2004 – January 31, 2005). RESULTS: There were 90 reported instances of laser illumination during the study period. A total of 53 reports involved laser exposure of commercial aircraft. Lasers illuminated the cockpit in 41 (46%) of the incidents. Of those, 13 (32%) incidents resulted in visual impairment or distraction to a pilot, including 1 incident that resulted in a reported injury. Nearly 96% of these reports occurred in the last three months of the study period. There were no aviation accidents in which laser light illumination was found to be a contributing factor during the period. CONCLUSION: The study of laser illumination incidents can identify operational problems in the aviation environment. Improved reporting and analysis of laser events enhances aviation safety by providing the FAA with data necessary to assist in the development of methods for mitigating the effects of laser exposure.

*Topic Summary:* The relationship between laser illumination incidents and the visual impairment of civil airmen that can result in operational problems in the aviation environment is described.

Topic: Neurophysiology / Vision

Ron W. Montgomery B.S., Van B. Nakagawara O.D., Kathryn J. Wood CPOT

**AIRCRAFT ACCIDENTS AND INCIDENTS ASSOCIATED WITH VISUAL DISTURBANCES FROM BRIGHT LIGHTS DURING NIGHTTIME FLIGHT OPERATIONS.**

INTRODUCTION: Preservation of optimal night vision is important for pilots operating an aircraft at night. When the eyes are adapted to low-light levels, exposure to bright light can result in temporary visual impairment due to glare, flash-blindness, and afterimages. The purpose of this study was to investigate operational problems experienced by civilian airmen exposed to bright light sources while performing nighttime aviation activities. METHODS: The National Transportation Safety Board (NTSB) Aviation Accident and Incident Data System (Jan 1982 to Feb 2005) and the Federal Aviation Administration (FAA) Accident/Incident Data System (Jan 1978 to January 2005) were queried using terms associated with night vision problems. Accident



and incident reports annotated with one or more of these terms were reviewed to determine whether vision difficulties resulting from exposure to bright lights contributed to the mishap. RESULTS: Vision problems resulting from exposure to bright lights at night were found to have contributed to 58 mishaps. Reports included 30 (NTSB) accidents and 28 (FAA/NTSB) incidents. The majority of accidents (57%) occurred during the approach and landing phase of flight. Incidents occurred most frequently while taxiing (54%) and during approach and landing (36%). CONCLUSIONS: Exposure to glare sources at night can affect an aviator's dark adaptation and has contributed to aviation accidents and incidents. The study of these events assists airport authorities in defining appropriate modification of existing airport lighting systems and eliminating hazardous lighting near air traffic corridors. Preventative measures for avoiding similar glare conditions that impair vision and compromise the safety of aviation operations at night will be discussed.

*Topic Summary: The relationship between glare sources and aviation accidents and incidents for civil aviation pilots is described.*

Topic: Aviation Medicine

Arvind K. Chaturvedi Ph.D., Dennis V. Canfield Ph.D., James E. Whinnery Ph.D., M.D.

### **EFFECTS OF SELECTIVE SEROTONIN REUPTAKE INHIBITORS ON PERFORMANCE AND BEHAVIOR: AN OVERVIEW**

INTRODUCTION: Although the biochemical pharmacology of selective serotonin reuptake inhibitors (SSRIs)—citalopram, fluoxetine, fluvoxamine, paroxetine, and sertraline—has been established, there has been a paucity of well-designed studies evaluating the effects of SSRIs on performance and behavior. Apparent association between the use of SSRIs and an increased risk of suicide has been suggested, but suicide is a possible outcome of depression itself. It has not been yet established whether such adverse effects are associated with pathophysiology of the disease and/or psychopharmacology of these drugs. METHODS: Therefore, a literature search and analysis was conducted on the effects of SSRIs on the performance and behavior of depressed and healthy human subjects. RESULTS: Increased recognition of fear in depressed patients can be normalized by citalopram. When combined with (–)-dihydroxyphenylalanine (l-dopa), citalopram induces an improvement of motor performance in depressed and non-depressed patients with idiopathic Parkinson's disease. Although exercise performance is not influenced by fluoxetine, fluoxetine and sertraline were found to improve cognitive function. Impaired cognitive performance in depressed patients was improved by fluvoxamine. Paroxetine has been indicated for short-term, generalized anxiety disorder. Abrupt discontinuation of treatment with paroxetine leads to deterioration in cognitive and psychomotor function, but these effects are not evident in patients receiving fluoxetine, sertraline, and citalopram. Paroxetine was found to effectively improve performance of older depressed patients. In non-depressed volunteers, sertraline was found to have no effect on either cognitive or psychomotor performance. The overall potential of SSRIs for inducing suicidal behavior has been conflicting. CONCLUSIONS: These complex, multi-facet effects warrant well-designed clinical studies with these psychotropic drugs. Findings from such studies would be helpful in defining the effects of SSRIs on the psychophysiological skills essential for flight safety.

*Topic Summary: Complex, multi-facet effects of selective serotonin reuptake inhibitors on performance and behavior.*



Topic: Flight Safety/Accident Investigation

Arnold A. Angelici Jr.

### **ACCIDENTS INVOLVING COMMEMORATIVE AIR FORCE AIRCRAFT 1968 TO 2005**

**INTRODUCTION:** The Commemorative Air Force (CAF) was founded in 1951 with four World War II-era aircraft and a mission to have a flying example of every aircraft that was flown during the war years, 1939 through 1945. The membership numbers more than 11,000 “Colonels” whose ages range from 18 to 100 years of age. They are divided into 70 different Wings, Squadrons or Detachments in 27 U.S. states and four countries. There are about 260 pilots registered, but only 213 are certified to fly these aircraft. The skill sets range from pilots with a minimum of 300 hours and a tail wheel endorsement to retired military and professional pilots with many thousands of hours of experience. The CAF’s collection consists of 140 aircraft representing 60 types from many different countries. All of the flying performed by the CAF is under 14 CFR Part 91. Since 1968, the CAF has lost 40 aircraft to accidents. **METHODS:** This paper examines the National Transportation Safety Board (NTSB) Probable Cause(s) of these accidents. **RESULTS:** CAF accidents resulted in 31 fatalities, eight serious injuries, nine minor injuries, and 23 uninjured crew or passengers. The causes as determined by the NTSB, revealed that they were due to the following: Pilot Error: 25 (62%), Maintenance: 10 (25%), combination of Maintenance and Pilot Error: three (7%), Incapacitation: one (3%), and Unknown: one (3%). **CONCLUSIONS:** Addressing the “pilot error” causes of these accidents, the CAF could consider concentrating on training, including ground based training through a formalized ground school syllabus stressing the flying parameters of the assigned aircraft and formal re-currency training. Suggestions also include the development of a program that addresses the intangible aspects of flying to reduce judgment and inattention errors.

*Topic Summary: 1) Is "Pilot Error" a result of poor training, complacency or is it an aeromedical issue? 2) Can an organization reduce "pilot errors" by increase in the amount or quality of training? 3) What aeromedical measures can be developed and put into effect to reduce "pilot error" type accidents?*

Topic: Aerospace Physiology

Arnold A. Angelici Jr.

### **CIVIL AEROSPACE MEDICAL INSTITUTE ALTITUDE CHAMBER REACTIONS SURVEY, 2000 TO 2004**

**INTRODUCTION:** The current Civil Aerospace Medical Institute (CAMI) altitude chamber was certified for human use in 1998. The Airman Education Division (AAM-400) operated the chamber and maintains chamber “flight” logbooks. **METHODS:** In the five-year period, 2000 through 2004, the flight logbooks were reviewed for number of flights, students, time above ground level (at pressures less than ambient), and reactions related to acute altitude exposure. **RESULTS:** During this five-year period, there were 362 flights with 3,786 students. The average flight time above ground level was 35 minutes, not including a 30-minute de-nitrogenation period and a brief climb to 6,000 feet mean sea level (MSL) and return to ground level (at 3,000

feet per minute) for a sinus and ear function check. The recorded altitude chamber reactions were: barotitis media (N=122), barosinusitis (N=26), barodontalgia (N=1), abdominal distress (N=3), hyperventilation (N=3), and decompression sickness (DCS, N=2). Most of the symptoms resolved prior to returning to ground level by “climbing” the chamber to an altitude that provided relief from the trapped gas-related symptoms, having the student perform a Valsalva maneuver, or treating the student with a topical vasoconstrictor dispensed via a nasal spray. The DCS related symptoms subsided with the student’s return to ground level and breathing supplemental 100% oxygen. Of these reactions, only six were referred to a CAMI flight surgeon for evaluation. Their reactions resolved with no further follow-up required. **CONCLUSIONS:** Reactions that were reported by the students were mild and not unexpected. The training profile that is in current use provides the students a safe learning environment with a relatively small exposure to altitude-related adverse reactions.

*Topic Summary: 1) Safety of current FAA hypobaric training profile is safe and 2) Hypobaric training allows pilots to experience the effects of hypobarism in a safe and controlled environment.*

Topic: Flight Safety/Accident Investigation

Nicholas L. Webster, Charles DeJohn

### **CIVILIAN AIRSHOW ACCIDENT ANALYSIS**

**INTRODUCTION:** Aircraft accidents involving civilian airshow performers have been in the news over the past year. Interviews with airshow performers and a review of FAA guidance to airmen on aeromedical hazards indicate that the prime physiologic hazard is G-induced loss of consciousness. The purpose of this study is to determine the aeromedical hazards present in recent accidents and discuss how these hazards contribute to the overall risk to airshow flight. Additionally the study will discuss the risk of fatal accidents experienced by professional airshow pilots compared with the rest of civilian aviation. **METHODS:** Aircraft accident data were obtained from the National Transportation Safety Board (NTSB) database, the International Council of Airshows (ICAS), and the Civil Aerospace Medicine Institute (CAMI) autopsy database. Information on the number of airmen with current statements of acrobatic competency was obtained from ICAS. **RESULTS:** Data compilation show 39 total civilian U.S. airshow or airshow practice accidents were identified between 1997 and 2004. Thirty-three of the 39 accidents occurred during maneuvering flight, with 12 accidents involving vertical and horizontal + Gz maneuvers and 12 accidents involving rolling, spinning, or slicing maneuvers. **Discussion:** + Gz has long been known as a hazard to aerobatic flight, but there is little documentation on the hazards of rolling, spinning, and slicing maneuvers. Current guidance for acrobatic flight hazard information can be found in the Aeronautical Information Manual. There is information on the aeromedical effects of + Gz but limited information of the aeromedical effects of controlled rolling, spinning, spiraling, or slicing maneuvers. **CONCLUSIONS:** There was no difference in the number of maneuvering airshow accidents related to + Gz versus rolling or gyroscopic maneuvers. The study indicates a need for more detailed analysis and education of airshow pilots about the hazards of rolling or gyroscopic maneuvers.

*Topic Summary: 1) recent accident experience of airshow performers, 2) maneuvers leading to accidents, 3) current guidance provided to control hazards leading to these accidents.*

Topic: Flight Safety/Accident Investigation

Eduard Manuel Ricaurte, Charles Andrew DeJohn D.O., Robert Satterlee Jr.

### **INJURY ANALYSIS OF AN AIRLINE ACCIDENT.**

**INTRODUCTION:** On June 1, 1999, at 23:50:44 CDT American Airlines flight 1420, a McDonnell Douglas DC-9-82 overran the end of runway 4R during landing at Little Rock National Airport in Little Rock, Arkansas. The flight departed from Dallas Fort Worth International Airport at 22:40 with two flight crewmembers, four flight attendants, and 139 passengers aboard and touched down in Little Rock at 23:50:20. After the end of the runway, the airplane struck the instrument landing system (ILS) localizer array, passed through a chain link security fence and down a rock embankment 15 feet below the runway elevation. As a result, 11 people were killed, including the captain, 45 people suffered serious injuries, 65 people sustained minor injuries; and 24 passengers were uninjured. **METHODS:** A review of the autopsy reports of non-survivors, and hospital records of survivors was conducted. Injuries sustained by each occupant, as well as toxicology findings, were classified using the Abbreviated Injury Scale 1990 Revision. Also, injury patterns were compared with similar aircraft accidents. **RESULTS:** Gender distribution for the 110 injured survivors was 51 females and 60 males with an average age of 41 years and an average weight of 148.5 lbs. The most frequent injury by body region was lower extremities, followed by upper extremities, and thorax. Among the seven females and four males non-survivors, the three most frequent injuries were burns (82% of decedents) followed by thoracic (55% of decedents), and head injuries (45% of decedents). Upper and lower extremities injuries had the same distribution, with 36% of decedents for each one. The gender distribution for survivors with no injuries was 12 females and 12 males. **CONCLUSIONS:** Injury analysis in both survivors and fatally injured occupants showed a pattern consistent with post-crash fire, deceleration forces, and probable evacuation restrictions due to lower extremities injuries.

*Topic Summary:* 1) examine injuries in aircraft accidents using the Abbreviated Injury Scale Update 1998, 2) compare fatal injury distribution in male and female occupants, and 3) analyze injury patterns in survivors and fatally injured occupants in an aircraft accident.

Topic: Medical Standards / Aircrew Health

Estrella M. Forster

### **CHARACTERISTICS OF THE CIVIL AVIATION FEMALE PILOT (PANEL INTRODUCTION)**

The history of women in aviation began with E. Lillian Todd, the first woman to design and build an aircraft (USA, 1906). That year, Theodore Roosevelt was president, Einstein introduced his theory of relativity, and Susan B. Anthony died. Yet, her quote “failure is impossible,” remains with us today, particularly as it relates to the continued success of women in aviation. The first woman to pilot an aircraft was Therese Peltier, of France and the year was 1908. Blanche Stuart Scott, the first woman to solo an aircraft on 2 September 1910, followed this historic achievement. Months later, Lillian Todd’s airplane took flight: “After years of effort, Miss E. Lillian Todd, of No. 131 West 23rd street, realized her ambition yesterday, when she had

the pleasure of seeing a biplane, the work of her hands and brain, fly across the Garden City aviation field... A good sized crowd was on hand to witness the first attempt to fly the biplane. Mr. Didier Masson was the aviator. He ran the machine across the ground, then went to the air for twenty feet and made a turn at the far end, returning to the starting place, where he was enthusiastically received by Miss Todd and the crowd..." [New York Herald, 8 November 1910]. Almost a century later, more than 100,000 women aviators have taken to the skies. This panel will describe the characteristics of the female pilot based on information proceeding from the Federal Aviation Administration's medical certification process, the National Transportation Safety Board's database, and the FAA Civil Aerospace Medical Institute's Aerospace Medical Research Toxicology and Autopsy databases. The panel will include a description of the bioinformatics tools utilized to examine the millions of aeromedical records describing U.S. civil aviation female pilots and their flight experience over the 1993 – 2004 period.

*Topic Summary: Describe the civil aviation female pilot.*

Topic: Medical Standards / Aircrew Health

James E. Whinnery Ph.D., M.D., Estrella M. Forster M.S., Ph.D., Stephen J. Véronneau M.D., M.S., Connie L. Peterman, Paul Rogers B.S., Marc Davidson, Warren Steven Silberman

### **AEROMEDICAL CHARACTERISTICS OF FEMALE CIVILIAN PILOTS: INTRODUCTION**

Women continue to make ever-increasing contributions to aerospace operations in the space, military, and civilian flying arenas. They have a proud history of great successes, along with devastating losses. With the increasing participation of women in flight, it is important to establish a solid basis for following and understanding the aeromedical aspects of their activities in the aerospace environment. As the medical research arm of the Federal Aviation Administration (FAA), a regulatory agency, we established a data system to evaluate the aeromedical aspects of women in civilian aviation over the 11-year period from 1993 through 2003. We utilized data from the Document Imaging Workflow System (DIWS) containing medical certification information and linked it to the Civil Aerospace Medical Institute (CAMI) databases for development of the Aviation Medical Research Scientific Information System (AMRSIS). The AMRSIS is also linked to the CAMI Forensic Toxicology Database, the National Transportation Safety Board database, and the Accident-Incident Database System so that an integrated epidemiological description of the available aeromedical characteristics of over 100,000 women that were medically certified for civilian flight during the 11-year period was possible. Establishment of a defined methodology for developing an integrated bioinformatic analysis of female pilots forms the basis for documenting historical trends and the future understanding of the performance aspects of women in civilian aviation. This information is essential for ensuring optimal aeromedical certification standards and continued aviation safety of women in civilian aviation.

*Panel Topic Summary: The civil aviation female pilot: Historical aspects*

Topic: Medical Standards / Aircrew Health

Connie L. Peterman, Paul B. Rogers B.S., Stephen J.H. Véronneau M.D., M.S.

**CIVIL FEMALE AVIATOR PANEL 1993 TO 2005: WAREHOUSE DESIGN**

**INTRODUCTION:** A scientific information system was developed at CAMI to assist in research efforts associated with medical certification decision-making. The Bioinformatics Research Team at CAMI uses informatics to study issues associated with medical certification decisions to ensure safety of flight. Significant data challenges exist relative to the integration and analysis of very large datasets associated with civil aviation. **METHODS:** The CAMI aviation safety/medical certification data warehouse, a read-only system, was created with data from varying time periods. Data includes NTSB mishap data, FAA Accident Incident data, airmen registry data (combined with medical certification data), toxicology data and autopsy data. The research methodology, developed on records from the CAMI warehouse, was used to create the aerospace medical research scientific information system (SIS) that contains new metrics for comparing groups of aviators. **DISCUSSION:** We will discuss the methodologies developed to create new metrics, “active-airman” and “certification-months-contributed,” which show promise in comparing groups of aviators with various pathologic conditions. **CONCLUSION:** CAMI was successful in integrating into a single prototype scientific information system various groups of related data to allow research analysis of potential safety related issues.

*Topic Summary:* Scientific Information Systems in aviation medical research.

Topic: Medical Standards / Aircrew Health

Stephen J. Véronneau M.D., M.S., Connie L. Peterman, Paul Rogers B.S.

**CIVIL FEMALE AVIATOR PANEL 1993 TO 2005: WAREHOUSE ANALYSIS**

**INTRODUCTION:** The scientific information system (SIS) at CAMI was previously employed to analyze atrial fibrillation in civil aviators. Information has been retrieved to enable a comprehensive panel presentation of the female civil aviator. **METHODS:** The aviation safety/medical certification data SIS warehouse at CAMI was reviewed for the inclusive period 1993 to the present. Approximately 7.9 million examinations that led to a medical certificate being issued (active airmen) were matched to outcome data from FAA and NTSB mishap datasets. The 487,310 exams that resulted in the issuance of medical certificates to females were examined with regard to continuous variables (age, flight time - total and last six months, months active flying, experience) and categorical variables (year, gender, class medical issued, medications, pilot rating, and accident occurrences.) A measure was developed to track pilots who enter and exit from valid medical certification. Factor analysis was employed to generate an experience variable from total and last 6-month flight hours along with pilot rating. **DISCUSSION/RESULTS:** A data anomaly was discovered and fixed, adding 1.2 million pilot exams, 4,234 pilots and 4,245 mishaps. The number of active female pilots was stable from year to year (~44-46,000) representing 7% of the total pilot population. The number of female pilots was 109,415 from 1993 to the present. A “certification-months-contributed” metric can compare aviators with various pathologic conditions and documents the extent of “churn” in pilots maintaining medical certification status and thus active pilot status. Most females participated for

3-4 years of the 11-year period, with 7% of female pilots participating for the full 11 years of the review. **CONCLUSION:** The mean age of female aviators increased by approximately one year over the 11 years reviewed. Female pilots, mean age 36, were younger by six years than male pilots, mean age 43, at the end of the study period. Our measure of experience showed a small average decline over the study period.

*Topic Summary:* 1) Female pilot demographics and 2) Using large numbers of aviation electronic medical records in research.

**Topic: Medical Standards / Aircrew Health**

Estrella M. Forster M.S., Ph.D., Stephen J. Véronneau M.D., M.S., James E. Whinnery Ph.D., M.D., Connie L. Peterman, Paul Rogers, Marc Davidson

### **AVIATION ACCIDENTS OF THE CIVIL AVIATION FEMALE PILOT**

**INTRODUCTION:** On July 21, 1911, Denise Moore crashed while on a solo flight in France. She was 35 and the first woman killed in an airplane. Harriet Quimby became the first licensed female pilot in the United States (August 1, 1911) and less than a year later, she became the first woman to fly across the English Channel. On July 1, 1912, while flying in the Third Annual Boston Aviation Meet, her monoplane unexpectedly pitched forward, ejecting her and a friend. Quimby, who had written about safety precautions in flying, was not wearing a safety belt. She was 37 at the time of the tragedy. **METHODS:** The Federal Aviation Administration (FAA) Civil Aerospace Medical Institute (CAMI) Aerospace Medical Research Scientific Information System (AMRSIS) was utilized to determine the characteristics of civil aviation female pilots who had experienced an accident or incident while in-flight during the period 1993 to 2003. The AMRSIS process integrated information from the National Transportation Safety Board (NTSB) database and the Document Imaging Workflow System used in the medical certification process. **RESULTS:** We reviewed a total of 7,911,739 records of medically certified, active male and female pilots, representing 1,427,223 individuals. Females comprised 487,310 of the population of records (6.16%), representing 109,415 individuals (7.67%). Of these 7,911,739 records, 20,191 (.26%) were associated with NTSB events (accidents and incidents), of which 736 records (3.65%) represented 717 individual female aviators (17 aviators were associated with two NTSB reports and one with three). We will discuss details of the NTSB events and the aeromedical characteristics of these aviators. **CONCLUSION:** This study characterizes the civilian female pilot with a goal of integrating all the aeromedical, certification, and safety aspects of their career as aviators and aids in deriving safety strategies of specific interest for this population.

*Topic Summary:* NTSB events of the civil aviation female pilot.



Topic: Flight Safety/Accident Investigation

Eduard Manuel Ricaurte M.D., Charles Andrew DeJohn, Robert Satterlee Jr.

### **INJURY ANALYSIS OF FATAL ACCIDENTS INVOLVING WOMAN PILOTS**

**INTRODUCTION:** From January 1993 through December 2004 there were more than 25,000 aircraft accidents in the U.S. involving all types of operations. Approximately one fifth of these accidents (5,236) were fatal. During the same period, 698 female pilots-in-command were involved in aircraft accidents. Fatal injuries occurred in 101 female pilots, representing 14% of accidents involving female pilots. **METHODS:** A search of the NTSB Accident and Incident Database by the FAA National Aviation Safety Data Analysis Center for aircraft accidents resulting in fatalities of female pilots-in-command was conducted. In addition, demographic and injury description data were obtained from the CAMI Autopsy and Injury Database for 63 fatally injured female pilots. The Abbreviated Injury Scale 1990 Revision (AIS 90) was used to classify injuries sustained by the 63 fatally injured women. By comparison, during the same period, 2,305 autopsies of male pilots-in-command entered into the CAMI Autopsy Database were analyzed. Demographic and injury description data were compared between the male and female pilot's autopsies and AIS scores. **RESULTS:** The women studied ranged in age from 20 to 74 years, while the male pilots ranged in age from 17 to 91 years. The four most frequent injuries by body region in female pilots were: 1) thorax; 2) lower extremities; 3) abdomen and pelvic contents; and 4) head. By contrast, the results from 2,305 male pilot's fatal injury descriptions, showed that the most frequent distribution of injuries by body locations were: 1) thorax; 2) lower extremities; 3) head; and 4) upper extremities. **CONCLUSIONS:** A comparison of fatal injuries sustained by female pilots-in-command with injuries sustained by male pilots-in-command, showed a slightly different injury pattern. Further studies are needed to better understand the effect of gender in fatally injured pilots-in-command.

*Topic Summary:* To compare fatal injury patterns of female pilots.

Topic: Medical Standards / Aircrew Health

John W. Soper Ph.D., Arvind K. Chaturvedi Ph.D., Russell J. Lewis Ph.D., Dennis V. Canfield Ph.D.

### **FEMALE PILOT FATALITIES IN CIVIL AVIATION ACCIDENTS: TOXICOLOGICAL FINDINGS**

**INTRODUCTION:** The number of fatal aviation accidents involving female pilots is relatively small in comparison to the number of accidents involving male pilots. No specific pattern has been established with respect to the toxicological findings in the female versus male pilot fatalities from aviation accidents. Therefore, this study was conducted. **METHODS:** The Civil Aerospace Medical Institute (CAMI) maintains a database containing toxicological findings and other relevant information pertaining to fatal aircraft accidents from which biological specimens are submitted to CAMI. This database was searched over the 15-year period (1990-2004) for any trends that could distinguish postmortem toxicological findings in certificated female pilots as compared with male pilots. **RESULTS:** Female pilots constituted only 175 out of 5540 fatal pilot cases (3%) received for analysis by the CAMI Laboratory. Ethanol at concentrations of  $\geq 0.1$



0.04% (w/v) was found in 3% of the 175 female pilots, and 7% of the 5365 male pilots. Controlled dangerous substances were found in 6% of the female and 8% of the male pilots. Prescription medications were found in 12% of the female and 14% of the male pilots, while non-prescription medications were found in 20% of the female and 15% of the male pilots. Nineteen percent of the female and 11% of the male pilots reported taking various medications on their medical certificate applications. The average age was 44 years (range: 17-77) for female pilots and 49 years (range 17-91) for male pilots. CONCLUSION: Findings from this study reflect that (i) more than twice as many male pilots had significant alcohol levels, as compared to female pilots, and (ii) while percentages of the various categories of drugs found were quite similar for both sexes, the female pilots reported taking medications at nearly twice the rate of male pilots.

*Topic Summary: Toxicological findings in civil aviation accident female pilot fatalities.*

Topic: Aviation Medicine

Estrella M. Forster, Eduard Manuel Ricaurte

Iberoamerican Aerospace Medical Association

**ADVANCES IN AEROSPACE MEDICINE IN LATIN AMERICA**

This year the Iberoamerican Association of Aerospace Medicine panel celebrates nine years of sharing scientific advances in operational and clinical aerospace medicine in the Spanish language. It will be a pleasure to present our findings in a place like Orlando, which offers a rich Hispanic culture and is one of the most visited US cities by Latin-Americans. The panel, chaired by the distinguished Dr. Finkelstein of Argentina and co-chaired by the esteemed Dr. Vargas of Peru, will commence with the paper entitled “Santos Dumont: 100 Years of the Dream,” by Dr. Madrigano of Brazil. He will review the achievements of the Brazilian aviation pioneer, who was the first in the world to take off, fly, and land a plane by its own means. The panel will continue with the paper entitled “Silent Abdominal Aortic Aneurysm in Pilots” by Dr. Cima of USA, who will present a literature review on the topic covering the last 10 years. Dr. Gonzales, of Colombia, will continue the session by discussing a study on the “Fatigue Effects on Flight Attendants Cognitive Process.” Dr. Salazar, of USA, will next introduce the operational aspect of the session with a paper entitled “Night Vision Goggles in Commercial Aviation.” He will emphasize the importance of this technology in enhancing situational awareness. Next, Dr. Ciancio of Argentina will present recommended guidelines to prevent or mitigate cosmic radiation exposure caused by solar flares. His paper is entitled “What do Latin Americans do when the Sun Explodes?” Finally, Dr. Russomanno of Brazil will close the panel by presenting an interesting study on space motion sickness, with a paper entitled “The Effect of Scopolamine on Mental Performance during Microgravity Simulation.”

*Topic Summary: Scientific advances in operational and clinical aerospace medicine in the Hispanic scientific community.*

Topic: Neurophysiology /Vision

Van B. Nakagawara O.D., Ron W W. Montgomery B.S.

**THE EFFECTS OF OUTDOOR LASERS PROJECTED IN THE NAVIGABLE AIRSPACE.**

Over 500 incidents involving the illumination of aircrew members by laser light have been reported in the past decade. As a consequence of several serious incidents, Federal Aviation Administration (FAA) Order 7400.2 was revised to institute new guidelines for flight-safe exposure limits in specific zones of navigable airspace. This presentation will review a study that evaluated pilot performance in a Boeing 727-200, Level C, flight simulator using four levels of 532-nm laser illumination (none, 0.5, 5, and 50 mW/cm<sup>2</sup>) and three operational maneuvers. Results indicated that the 5 mW/cm<sup>2</sup> Critical Flight Zone (CFZ) level listed in revised FAA Order 7400.2 provides a sufficient level of protection for aviators within the CFZ. Additionally, new guidance provided by the recent publication of two FAA Advisory Circulars (AC No: 70-1 and 70-2), which establish proper notification procedures for planned outdoor laser operations and the reporting of laser illumination incidents to appropriate authorities, will be reviewed.

*Topic Summary: The relationship between laser light illuminations of civil aviation pilots and countermeasures established to mitigate such exposures is described.*

Topic: Flight Safety/Accident Investigation

Nicholas L. Webster M.D., M.P.H., Charles DeJohn

**AVIATION SAFETY: FY 2005 IN REVIEW - PANEL INTRODUCTION**

Representatives from each of the U.S. Military Safety Centers and the Civil Aerospace Medical Institute, Federal Aviation Administration will present respective information on aviation safety and adverse aviation events during fiscal year 2005. Discussion will center on mishap/accident analysis of both mechanical and human causal factors. Hazardous trends will be further discussed and compared to previous years. Updates will be presented on the progress of ongoing intervention strategies designed to help mitigate and eliminate identified hazards.

*Topic Summary: insight into development of data driven intervention strategies based on analysis of mishaps during the past fiscal year and previous years.*

Topic: Flight Safety/Accident Investigation

Charles Andrew DeJohn, Nicholas L. Webster M.D., Julie G. Larcher

**CIVIL AVIATION IN 2005**

The Civil Aerospace Medical Institute Medical Research Team supports Federal Aviation Administration (FAA) medical certification, Aviation Medical Examiner education, and the FAA safety programs. The Team provides research findings and accident investigation facts to the

FAA, National Transportation Safety Board, industry, other government agencies, academia, and the media. Research data and education are also provided to foreign industry, government agencies and academia. In addition, the team works with other safety elements within the FAA such as the Office of Accident Investigation, Office of System Safety, and the Office of Aviation Research to promote safe and efficient aviation operations worldwide. Safety statistics for 2005 will be presented and compared to previous years. Developments and challenges in FAA aerospace medicine and safety research will be discussed.

*Topic Summary:* Most significant hazards to civilian aviation in 2005.

Topic: Medical Standards / Aircrew Health

Charles Andrew DeJohn D.O., Warren Steven Silberman D.O., Julie Granados Larcher

### **THE PERIODICITY OF PILOT FIRST-CLASS MEDICAL EXAMINATIONS**

**INTRODUCTION:** The Federal Aviation Administration (FAA) often issues over 650 first-class medical certificates each day. Airmen are required to be reexamined every 6 months to maintain their first-class medical status. The FAA is exploring the option of extending the reexamination period for pilots under age 40 to reduce the Aeromedical Certification Division workload and ease the burden on pilots. This study explores whether the reexamination period could be safely extended. **METHODS:** A search of the FAA medical database showed that 659 airmen were issued first-class medical certificates on July 1, 1999. Of the 659 airmen, 312 were under age 40. We randomly selected a sample of 100 active airmen from the under age 40 population. FAA medical records for the sample of 100 airmen were searched for predefined, medically significant pathology codes assigned by the Aeromedical Certification Division between July 1, 1999 and July 1, 2002. Pathology codes were grouped by six-month intervals from six to 36 months. The proportion of medically significant pathology codes assigned in the different intervals were then compared. **RESULTS:** Three hundred and forty-four physical examination intervals, between 6 and 36 months, were identified from the sample of 100 airmen under age 40. Fifty-nine percent were six-month intervals, 40% were 12-month intervals, 0.5% were 18-month intervals and 0.5% were 24-month intervals. None of the 100 airmen in the sample had examination intervals in excess of 24 months. A medically significant pathology code was assigned during one of the 204 6-month examination intervals, while another was assigned during one of the 136 12-month examination intervals. There was no significant difference in the proportion of medically significant pathology codes assigned between the six and 12-month examination intervals. **CONCLUSIONS:** The data suggest the period required to maintain a first-class FAA medical certificate for pilots under age 40 might be extended to 12 months without missing a significant amount of important pathology.

*Topic Summary:* 1) FAA resources necessary to certify and issue first-class medical certificates. 2) The amount of significant pathology discovered using different examination intervals. 3) A comparison of the standard six and 12-month physical examination intervals used for U.S. first class medical certificates.

Topic: Aerospace Physiology

Dennis Burian, Dennis Canfield, James Whinnery

**MOLECULAR MEDICINE TAKES OFF: MICROARRAY ANALYSIS OF GENE EXPRESSION IN AEROSPACE MEDICINE**

Since the sequencing of the human genome was completed, the field of molecular medicine has come of age. Investigation of gene expression changes in response to disease states has become commonplace in the biomedical literature. Every major pharmaceutical and biotechnology company now sports a research group devoted to finding therapeutic targets based on gene expression changes in response to their favorite disease(s). As a result, definitive molecular signatures for many different diseases including diabetes and a variety of cancers have been determined. However, for a variety of reasons, factors that affect aviation have not yet received the same scrutiny from the molecular point of view. This presentation will focus on the use of microarray technology to investigate gene expression changes in response to factors that affect aviation safety. The advantages of microarray analysis as a whole transcriptome screening tool will be discussed. Data from investigations of the molecular effects of short-term mild alcohol use will be used to illustrate the advantages and disadvantages of this analytical methodology for aerospace applications.

*Topic Summary: 1) Increase the awareness of aerospace professionals as to the uses and benefits of microarray analysis of gene expression and 2) Demonstrate that microarray analysis can detect the subtle changes in gene expression that result from aerospace related human factors.*

Topic: Aerospace Physiology

Dennis Burian, Doris Kupfer, Dennis Vincent Canfield, Whinnery James

**MOLECULAR MEDICINE TAKES OFF: QUANTITATIVE PCR, A QUICK AND INEXPENSIVE METHOD FOR GENE EXPRESSION ANALYSIS**

The wealth of knowledge found in the current biomedical literature delineating the molecular basis of disease has become almost overwhelming. Microarray gene expression analysis has been shown to be a powerful tool for discovering molecular signatures for diseases, including various cancers and diabetes, and in our lab, aerospace medicine related factors such as mild alcohol use and fatigue. Microarray analysis is well suited to the discovery phase of a new investigation but has characteristic drawbacks as well. As a whole transcriptome screening technique, it is computationally intensive, relies heavily on statistical analysis, is relatively insensitive to small changes in gene expression and is expensive. Quantitative PCR (QPCR) has been the method of choice for the validation of microarray experiment results. QPCR is a targeted, gene-specific technique that lacks the power of microarray analysis to simultaneously screen large numbers of genes but is well suited to validate microarray gene expression data. It requires little computational power beyond the data analysis software and a spreadsheet, is more sensitive and quantifiable, and the equipment and reagents are much less expensive. Data from the validation phase of a study investigating changes in gene expression in response to mild short-term alcohol use will be used to demonstrate the usefulness of this technique to validate microarray expression

data. Results demonstrating the ability of this method to expand upon findings of a microarray study within candidate pathways will be presented as well.

*Topic Summary: Introduce quantitative PCR as a method to investigate gene expression changes in aerospace medicine and Demonstrate the usefulness of quantitative PCR to validate microarray expression analysis.*

Estrella Forster

### **MANAGEMENT OF RD&E PROGRAMS: QUALITY MANAGEMENT IN APPLIED RESEARCH**

The Merriam-Webster dictionary defines “standard” as “a conspicuous object (as a banner) formerly carried at the top of a pole and used to mark a rallying point especially in battle or to serve as an emblem.” According to Wikipedia, the modern primary meaning evolved through similar symbolism: “A quality or measure which is established by authority, custom, or general consent.” Standards are common of manufacturing and service enterprises and usually related to managerial concerns with quality control or product specification. Thus, the scientific research community has normally been impervious to these developments and typically considers all discussions of quality or standards akin to annoying team-building exercises and strictly related to the manufacturing of widgets. Meanwhile, Research & Development investment programs and research laboratory managers are constantly seeking an improved approach to evaluate the cost, benefit, or “value-added” of research products. Yet we have difficulty defining these products or their impact. We are often required to justify our scientific research goals in terms of a financial statement. Indeed, the search for the truth has become a search for the dollar and its customer satisfaction. Finally, it is unreasonable to suggest to any scientist that standardization would lead to the “Eureka!” of scientific discovery. Nevertheless, the fact remains that quality in research is not always evident to the observer (i.e., the sponsor of the research) and often difficult to measure, if measured at all beyond the peer review process. This panel will discuss the implementation of the International Organization of Standardization (ISO) quality standards in a research organization and how it has provided a framework for the improved definition of research processes and their products. The panel discussion will include an introduction to ISO standards, their application in a government research organization, software utilized to track progress, and the resulting benefits from this initiative.

Nelda J. Milburn and Estrella M. Forster

### **MANAGEMENT OF RD&E PROGRAMS: QUALITY IN AEROSPACE RESEARCH ORGANIZATIONS**

The idea of quality is not new. The concept has probably been thriving since one caveman traded goods or services with another. Relatively speaking, the U.S. government is a latecomer to the quality bandwagon with the introduction of unified military standards during World War II

and even more recently the Office of Aviation Safety's decision to become ISO 9000-certified. ISO (International Organization for Standardization) began in 1947 and consists of more than 150 member countries. The objective of ISO is to develop common international standards in many areas. The quality management standards that apply to all types of organizations, regardless of their size, product, or nature, are contained in a set of 3 documents called ISO 9000, 9001, and 9004. This presentation will discuss those 3 documents and their relevance to aerospace research. The quality management system requirements stated in ISO 9001 are simply sound business principles that can benefit any organization. ISO 9001 addresses many core issues related to organizations such as communication, leadership, continual improvement, measurable objectives, control of nonconforming products, and customer focus, just to name a few. Defining quality is as specific and individualistic as declaring that someone is knowledgeable, beautiful, or skilled. Just as determining one's degree of knowledge is applicable to a specific field of study, and beauty is said to be in the eye of the beholder, and skill is quantifiable only within an explicit set of parameters; quality is definable only to the "degree to which a set of inherent characteristics fulfils requirements" (ISO 9000:2000, 3.1.1, p. 7). Therefore, the customer defines quality by the degree to which he/she believes the product (or service) meets the customer's needs. Consequently, quality is a vital interest for aerospace research because it is defined by the extent to which the research products meet the sponsor's needs.

E. M. Forester, N. J. Milburn, J. E. Whinnery, and D. Schroeder

#### **MANAGEMENT OF RD&E PROGRAMS: THE APPLICATION OF ISO STANDARDS IN RESEARCH ORGANIZATIONS.**

The International Organization for Standardization (ISO) developed a set of quality standards applicable to any organization, including ISO 9000:2000 and ISO At the direction of the Federal Aviation Administration (FAA) Office of Aviation Safety (AVS) and its Office of Aerospace Medicine (AAM), these standards were implemented at the Civil Aerospace Medical Institute (CAMI), including its Human Factors and Aeromedical Research Divisions. The application of ISO CAMI was launched in November 2004 and is scheduled to be audited for certification in February 2006. The implementation of ISO standards included the quality objectives in line with the FAA's Flight Plan, AVS, and AAM Business and Performance Plans. The research processes of both Divisions were reflect a common approach to quality management. As a result, 2 Quality Management System (QMS) processes were developed to define our research Knowledge proceeding from scientific research activities and Involvement in organizational and scientific workgroups. These processes were also described by flowchart that tracks the development and delivery of tangible and intangible products. Tangible products included scientific publications, consultation reports, and affidavits. Intangible products included data-mining, academic interactions, and collaborative efforts with other research institutions. Managerial concerns were incorporated in the QMS, including document control, resources, training, and agreements with academia, government, and industry. To assess the efficacy of the QMS, metrics were derived in terms of 1) product conformance, 2) process performance, and 3) customer satisfaction. The Research Activity Monitor software was utilized to track progress. The goal of the presentation is to detail how our approach to ISO standardization evolved into a



QMS that is applicable research organizations and may facilitate the development of common practices across the scientific research community.

Dennis Canfield, James Whinnery

### **MANAGEMENT OF RD&E PROGRAMS: THE RESEARCH ACTIVITY MONITOR**

The success of electronic programs to monitor research activities depends on developing painless methods of trapping data and creating reports with minimal on the timely completion of the research. In the oversight of research programs there exists a delicate balance between capturing and reporting data and the actual research being conducted. This balance requires an automated system that a user can access quickly and enter data needed for tracking and progress and products. In large organizations with numerous projects it is essential to present the user scientist with only the information they are assigned and require searching through a long list of activities irrelevant to their work. The Research Activity Monitor (RAM, © 1998-2004, DiscoverSoft Development, LLC, City, OK) was developed to assist management in capturing and tracking tasks, activities, accomplishments, and products. Broad general activities, specific subtasks, categories, and sub-categories can be defined. Individuals can easily review work assigned only to them and formulate data entries. Managers and alike can quickly review work in progress and define new assignments. Administrative reports are automatically produced from project defined reporting Permission levels granted by a RAM administrator control user access to all program components. Integration of a RAM with management initiatives, such as International Organization for Standardization (ISO) 90001 certification, can facilitate the concurrent accomplishment of both research and the management The ever-increasing burden of management activities on research programs requires innovative techniques to reduce the time spent on administrative processes and permit scientists to accomplish their primary research mission.

A. K. Chaturvedi, J. W. Soper, P. S. Cardona, and D. V. Canfield

### **MANAGEMENT OF RD&E PROGRAMS: APPLICATION OF QUALITY INSTRUMENTS IN AEROSPACE MEDICINE RESEARCH OPERATION**

INTRODUCTION: Under the aerospace medicine research activity at the Federal Aviation Administration's (FAA's) Civil Aerospace Medical Institute (CAMI), biological specimens from aircraft accident fatalities are also toxicologically evaluated for the presence of combustion gases, ethanol, and drugs. Throughout this activity, a high level of quality is maintained and continuous quality improvement (CQI) is always sought. METHODS: With this philosophy, various instruments of quality control (QC), quality assurance (QA), quality system (QS), and CQI are routinely applied/used, or planned to be instituted, at CAMI. These instruments and associated applications are briefly described herein. RESULTS: Research projects/protocols and reports/papers are subjected to multilevel internal and external reviews. Based upon the reviews, reports/papers are cleared for presentation/publication. The majority of them are also published in peer-reviewed open scientific journals. During toxicological evaluation, from receiving



samples to dispatching analytical reports, QCs are multilevel reviews, open/blind analytical controls, and participation in ethanol and drug proficiency-testing (PT) surveys from the FAA's CAMI Postmortem Forensic Toxicology (PFT) and College of American Pathologists (CAP) PT programs. QA is demonstrated by CAP and American Board of Forensic Toxicology (ABFT) accreditations of the CAMI laboratory. QS stems from the CAP and ABFT guidelines. For CQI, a laboratory incident reporting module was instituted. Based on these incidents, various corrective, preventive, and proactive approaches were taken, leading to overall improvement in the laboratory performance. Although most of these quality instruments have been applied/used proactively since 1991, additional quality instruments—DNA-profiling PT program focused on PFT, ISO 9001:2000 Quality Management System, and ISO 17025 General Requirement for the Competence of Testing and Calibration Laboratories—are being attempted for implementation at CAMI. CONCLUSION: Quality instruments in an operation effectively improve its performance and products on a continuous basis in a total quality management environment.

J. W. Soper, A. K. Chaturvedi, and D. V. Canfield

#### **MANAGEMENT OF RD&E PROGRAMS: BEYOND ISO-9001, LABORATORY CERTIFICATION UNDER ISO-17025**

Efforts that would lead to forming the International Organization for Standardization (ISO) began in 1906 with the International Electrotechnical Commission (IEC). The ISO organization officially began operations in 1947. Approximately 600,000 ISO certificates have now been awarded worldwide. These have been awarded to businesses, including many in aviation and other transportation-related industries, as well as government, educational, and other service-related entities. The Federal Aviation Administration, along with other governmental agencies, is moving toward accreditation under the ISO 9001-2000 program. Areas of concern under this program are described in five primary clauses. These include a description of the entities Quality Management System, Management Responsibility, Resource Management, Product Realization; and Measurement, Analysis and Improvement. In addition to the above-described program, specific laboratory accreditation is available through ISO/IEC 17025-2005 (general requirements for the competence of testing and calibration laboratories). This accreditation further expands the technical aspects of the ISO-9001 program and compresses most of its above-mentioned five clause areas into only two main clauses: Management Requirements and Technical Requirements. The objective of this accreditation process is to focus on the overall quality system management and technical operations for a laboratory. While specific checklists do not exist for accreditation under any of the ISO programs, five items of particular relevance exist in the standards with regard to eventual admissibility of testing results in a court of law. These are: (1) control of non-conforming testing, (2) validation of methods, (3) estimation of uncertainty of measurement, (4) measurement traceability, and (5) maintenance and proper calibration of laboratory equipment. These items and other particular challenges will be examined with regard to certification of testing and calibration laboratories within the federal government and the aerospace industry.

Lori Samuel and James Whinnery

## **MANAGEMENT OF RD&E PROGRAMS; DO YOU RESEARCH ACTIVITY MONITOR?**

INTRODUCTION: Tracking research projects is an elusive task. The Aerospace Medical Research Division of the Civil Aerospace Medical Institute has developed and implemented the Research Activity Monitor (RAM) to track and report all of its research products, processes and initiatives. Our research products are defined as publications, presentations, customer/stakeholder inspections, academic interactions, continuing education, and a host of other activities or items. METHODS: This presentation will convey findings gathered from a survey that pertains to lessons learned and improvements needed for RAM implementation as employees initiated data entry into the system. RESULTS: The results presented include the prioritization of suggested changes as well as benefits to an organization utilizing the RAM on a daily basis. The RAM facilitates meeting reporting requirements and contributes to ISO-9000 certification initiatives being implemented. One of the ISO-9000 requirements is to review how well we are meeting customer requirements. This review is accomplished by conducting quarterly Analysis of Data meetings. By logging all activities into the RAM, data is quickly and efficiently assembled to improve reporting requirements and reduce redundancies that previously existed. CONCLUSION: The adoption of a tracking system similar to the RAM can streamline the tracking process for research organizations, decrease suspense deficiencies, and assist organizations in achieving the ISO-9000 certification initiative. The long term, primary goal of this endeavor is to reduce the administrative burden on bioaeronautical scientists, thereby enhancing scientific productivity.

James Whinnery

## **MANAGEMENT OF RD&E PROGRAMS: AEROSPACE MEDICAL RESEARCH AND ISO 9000**

The Aeromedical Research Division is the medical research arm of the Federal Aviation Administration (a regulatory agency). The research is generally sponsored by components of the FAA that have specific questions relevant to improving safety, health, security, mediation of injury, and enhancing survivability of passengers and crew in civilian aerospace operations. Our research knowledge (as assembled in scientific reports, publications, and presentations) is the basis for proposed rules, advisory circulars, and technical standards orders that the FAA uses in its regulation of the civil aviation industry. Our goal is to harness the powerful advancements in science and medicine for unrelenting improvement of aerospace operations. The challenge in research planning and management is maintaining the resources and expertise, so that there is adequate flexibility to achieve current and future research, ranging from very conceptual, advanced projects through highly applied operational support activities. To meet the range of internal and external quality standards, including ISO 9000, it has become critical to use standardized processes and to carefully document the processes.

*Workshop Summary: Introduction to ISO standards, their application in a government research organization, software utilized to track progress, and the resulting benefits from this AAM initiative.*

*More information on human factors research can be found at  
the FAA Human Factors (ATOP-R&D) web site: <http://www.hf.faa.gov>*

Paul Krois  
FAA (ATO-P R&D Human Factors)



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